AUG 29 1997

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

AUG 29 1997

WARNING LETTER

558

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ref: No. 97-HFD-340-0801

David Shaw, Chief Executive Officer
Idexx Veterinary Services, Inc.
1 Idexx Drive
Westbrook, Maine 04092

Dear Mr. Shaw:

During May of 1997, Ms. Karen Hirshfield and Ms. Karen Robles, investigators with the Food and Drug Administration (FDA) San Francisco District, inspected the nonclinical laboratory facilities of Idexx Veterinary Services, Inc. in West Sacramento, California to assess compliance with the Good Laboratory Practice (GLP) regulations, Title 21, Code of Federal Regulations, Part 58.

During the inspection, the investigators observed a number of serious deviations from the GLP regulations. Their findings were listed on a Form FDA-483 (copy enclosed), which was presented at the conclusion of the inspection.

Following the review of the Form FDA-483, the inspection report, other data collected during the inspection, and Ms. Payne's written response dated June 6, 1997 (copy enclosed), we conclude that these are serious violations of the GLP regulations. The failure of management and the quality assurance unit (QAU) to exercise their responsibilities as required by Sections 58.31 and 58.35 is a serious violation and has wide spread consequences that adversely affect many other areas of GLP compliance.

Specifically, your Quality Assurance Unit failed to assure that equipment, personnel, records, and controls were in conformance with GLP regulations and with your own standard operating procedures (SOPs).

Not all of your equipment was maintained and calibrated according to the manufacturer's instructions, and you did not provide documentation that your procedures either met or exceeded the manufacturers' specifications. Examples were listed on the Form 483.

You had no written procedures for maintenance of the [redacted] and [redacted] Analyzers, or for operation of an autoclave.

You had no written procedures for documenting deviations in temperatures of refrigerators and/or freezers in three areas, and for remedial action in response to the deviations. You did not always document omissions in temperature records, and remedial actions taken after temperature deviations.

We request that you respond in writing within fifteen(15) working days of receipt of this letter and indicate to us your intentions to correct the GLP violations. Your response should include documentation to substantiate the corrective actions taken.

We consider these violations a serious matter and urge you to respond promptly. Failure to do so may result in further agency action.

If you have any questions concerning this matter or the GLP regulations, please contact:

C.T. Viswanathan, Ph.D.
Associate Director
Division of Scientific Investigations
Office of Compliance
Center for Drug Evaluation and Research
7520 Standish Place, Room 151
Rockville, Maryland 20855
Telephone # (301) 594-1023

Sincerely yours,

David A. Lepay, M.D., Ph.D.
Director
Division of Scientific Investigations, HFD-340
Office of Compliance
Center for Drug Evaluation and Research

Enclosures: Form FDA-483
IVS, Inc. letter dated June 6, 1997

cc:
David Johnson, Western Regional Manager
Diane Payne, Director of Research/GLP Compliance
Idexx Veterinary Services, Inc.
2825 KOVR Drive
West Sacramento, California 95605